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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,099	01/16/2001	Rebecca E. Cahoon	BB 1159	3054

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 08/26/2002 12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/744,099

Applicant(s)

Cahoon et al.

Examiner

Christian L. Fronda

Art Unit

1652



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 22, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-46 is/are pending in the application.
- 4a) Of the above, claim(s) 43-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-36, 39-42, and 46 is/are rejected.
- 7) ☒ Claim(s) 37 and 38 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Jan 16, 2001 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 6) ☐ Other

Art Unit: 1652

DETAILED ACTION

1. In the **PRELIMINARY AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT** dated 5/22/2002 (Paper No. 10), Applicants have canceled claims 13-33 and added new claims 34-47.
2. For examination purposes, new claims 44-47 are renumbered as claims 43-46 because claim number "43" is missing in the **PRELIMINARY AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT** dated 5/22/2002 (Paper No. 10).

Election/Restriction

3. Applicant's election without traverse of Group I, drawn to an isolated polynucleotide encoding a 3-dehydroquinase synthase and species of SEQ ID NOS: 5 and 6 (corresponding to new claims 34-42 and 46) in Paper No. 10 is acknowledged. Claims 43-45, drawn to a transgenic plant, method of making said transgenic plant, and seed, are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. The requirement is still deemed proper for reasons of record and is therefore made FINAL.
4. Claims 34-42 and 46 are under consideration in this Office Action.

Priority

5. Applicant's claim for domestic priority under 35 U.S.C. 119(e) of U.S. provisional application number 60/093,611, filed 07/21/1998, is acknowledged.

Drawings

6. The drawings filed on 01/16/2001 are accepted by the Examiner.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and

Art Unit: 1652

process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 34-36, 39-42, and 46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide comprising SEQ ID NO: 5 which encodes a polypeptide having 3-dehydroquinase synthase activity and an isolated polynucleotide encoding a polypeptide having 3-dehydroquinase synthase activity, wherein the amino acid sequence of the polypeptide comprises the amino acid sequence of SEQ ID NO: 6; does not reasonably provide enablement for any isolated polynucleotide encoding a polypeptide having 3-dehydroquinase synthase activity, wherein the amino acid sequence of the polypeptide and the amino acid sequence of SEQ ID NO: 6 have at least 80%, 90%, or 95% identity based on the Clustal alignment method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *re Wands* [858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)]. The *Wands* factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass any isolated polynucleotide encoding a polypeptide having 3-dehydroquinase synthase activity, wherein the amino acid sequence of the polypeptide and the amino acid sequence of SEQ ID NO: 6 have at least 80%, 90%, or 95% identity based on the Clustal alignment method. The specification provides guidance and examples for making an isolated polynucleotide comprising SEQ ID NO: 5 which encodes a polypeptide having 3-dehydroquinase synthase activity and an isolated polynucleotide encoding a polypeptide having 3-dehydroquinase synthase activity, wherein the amino acid sequence of the polypeptide comprises that amino acid sequence of SEQ ID NO: 6.

However, the specification does not teach the specific catalytic amino acids and the structural motifs which are essential for enzyme structure and activity/function. The state of the art as exemplified by Attwood et al. (Comput. Chem. 2001, Vol. 25(4), pp. 329-39) is such that "...we do not fully understand the rules of protein folding, so we cannot predict protein structure; and we cannot invariably diagnose protein function, given knowledge only of its sequence or structure in isolation" (see Abstract and entire publication). Furthermore, Ponting (Brief. Bioinform. March 2001, Vol. 2(1), pp. 19-29) states that "...predicting function by homology is a qualitative, rather than quantitative, process and requires particular care to be taken...due

Art Unit: 1652

attention should be paid to all available clues to function, including orthologue identification, conservation of particular residue types, and the co-occurrence of domains in proteins" (See Abstract and entire publication).

The standard for meeting the enablement requirement is whether one of skill in the art can make the invention without undue experimentation. However, the amount of experimentation to make the claimed polynucleotides is enormous and extensive, and entails selecting specific nucleotides to change (nucleotide deletion, insertion, substitution, or combinations thereof) in any polynucleotide encoding a polypeptide having the amino acid sequence of SEQ ID NO: 6 in order to make a polypeptide that has an amino acid sequence has at least 80%, 90%, or 95% identity to SEQ ID NO: 6, and then determining by enzymatic assays whether the polynucleotide made encodes a polypeptide that has 3-dehydroquinate synthase activity.

The specification does not provide guidance with respect to the specific catalytic amino acids and the structural motifs essential for enzyme structure and activity/function which must be preserved. Thus, searching for the specific nucleotides to change (nucleotide deletion, insertion, substitution, or combinations thereof) in any polynucleotide encoding a polypeptide having the amino acid sequence of SEQ ID NO: 6 in order to make a polypeptide that has an amino acid sequence has at least 80%, 90%, or 95% identity to SEQ ID NO: 6 is well outside the realm of routine experimentation and predictability in the art of success in determining whether the resulting polynucleotide encodes a protein that has 3-dehydroquinate synthase activity is extremely low since no information is provided by the specification regarding the specific catalytic amino acids and the structural motifs essential for enzyme structure and activity/function which must be preserved.

The Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific catalytic amino acids and the structural motifs essential for enzyme structure and activity/function which must be preserved. Without such a guidance, the experimentation left to those skilled in the art is undue. Claims 39-42 and 46 which depend from defective claim 34 are also rejected because they do not correct the defect of claim 34.

Claim Objections

9. Claims 37 and 38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 1652

Conclusion

10. No claim is allowed.

11. The reference made of record and not relied upon is considered pertinent to applicant's disclosure: Bischoff et al. (GenBank Accession L46847) teach a polynucleotide which has 43.7% identity to SEQ ID NO: 5 and encodes a dehydroquinase synthase (see the enclosed alignment).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. The Examiner can be contacted Monday-Friday from 8:30AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.



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Art Unit 1652